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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,093	10/19/2001	S. Rao Cherukuri	02325-25667	6757

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	
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11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/982,093	CHERUKURI, S. RAO	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 3-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 3-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and requests for continued examination under 37 CFR 1.114, all filed 08/24/07.

Claims 1 and 3-24 were allowed on 05/04/07 after examiner's amendment to claim 1 authorized by applicant's representative. The current amendment cancels claim 1 and amends claims 3, 4 and 8-24. New claims 25-27 are added. Claims 3-27 are thus pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/02/07 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

New claims 25 and 26 give the diameter of the caplet as ranging from about 1 millimeter to about 3 millimeter. The specification at the abstract and at paragraphs [0019], [0023] and [0074] of the published application and original claim 1 disclose and recite that the diameter of the caplet is from about 1 millimeter to about 7 millimeter. Paragraphs [0098], [0101], [0104] and [0107] of the published application disclose caplets having specific diameter of 3 millimeter and 1.3 millimeter. The specification as originally filed does not envision diameters in the range of about 1 millimeter to about 3 millimeters. This is new matter.

The above rejection may be overcome by removing the new matter from the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 25, 3-24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carnmelm et al. (US 4.053,632).

New claim 25 is a pharmaceutical product that comprises of a) a therapeutically effective amount of a pharmaceutical, b) at least one compressible material, and c) at least one lubricating material.

Carnmelm discloses synthesis of neuroleptic agents of the spiro amine type compound (abstract, title) and the compounding of the neuroleptic compounds into tablet formulations having diameters of 6 and 10 mm (Examples 21 and 22). Antipsychotics are neuroleptics and

meets the requirements for pharmaceutical in claims 25-27, 3, 4 and insomnia therapeutic of claim 5 and the antidepressant of claim 6. Carnmelm synthesizes neuroleptics (Examples 15) and combines it with lactose, starch and magnesium stearate (Examples 21), which is compressed to tablets with a diameter of 6 mm (Example 21) and 10 mm (example 22). Lactose meets the limitation of compressible material of claim 25 b). Magnesium stearate meets the limitation of lubricant in claim 25 c). Instant claims 7-24 list a number of pharmaceutical that are formulated as caplet with compressible material and lubricating agents. However lubricating agents such as magnesium stearate and compressible materials such as lactose or sorbitol are commonly known excipients used in the fabrication of tablets, and hence of caplets since caplets are coated tablets. Specifically, the large number of pharmaceuticals listed in claims 7, 11, 14, 17, 20 and 23 indicate that any of the drugs listed in those claims can be formulated as a caplet or coated tablet and would therefore be obvious to fabricate the tablet of Carnmelm using other pharmaceuticals as active agents. Regarding the % lubricant recited in claim 27, the artisan using the reference of Carnmelm would be able to use appropriate amount of the lubricant to fabricate the tablet of Carnmelm since about 1% of the magnesium stearate lubricant is within the recited amount of up to 5%, with an amount "of up to 5%" encompassing an amount of less than 5%.

The diameter of the tablet of Carnmelm is at 6 mm and 10 mm (Examples 21 and 22). The recited diameter is between 1 mm and 3 mm, which would be obvious because it is within the ordinary capabilities of the artisan to formulate tablets/caplets having specific diameters by the use of known/standard tabletting tools designed to produce specific diameters of the caplets.

6. Claims 3-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batista et al. (US 5,296,233)

Batista describes compositions that contain medicaments selected from acetaminophen, ibuprofen, loperamide, naproxen, pseudoephedrine, dextromethorphan, chlorpheniramine, and mixtures thereof (column 2, line 66 to column 3, line 1) and excipients such as microcrystalline cellulose, starch, hydroxypropyl methylcellulose and silicon dioxide (Example 1) with the composition compressed into caplets (column 3, lines 44-62). While ibuprofen is exemplified, Batista contemplates formulating any of the drugs listed according to the Example. Microcrystalline cellulose meets the limitation of compressible material of claim 25 and silicon dioxide meets the limitation of lubricant of claim 25. Regarding the amount of the lubricant of claim 27, there is no demonstration that the "up to 5%" of lubricating material provides unexpected results and further, it is within the ordinary knowledge of the artisan to use adequate amounts of lubricant as tableting aid required to provide tablet/caplet having the desired hardness, tablet injection from the tablet press/punch press. Using the teaching of Batista, the artisan would formulate the caplet of Batista using any drug including those recited in claims 3-8, 10-15 and 19-24.

The difference between the claims and Batista is that Batista is silent on the dimensions of the caplet. However, it would have been obvious to prepare the caplet having desired dimensions of length and diameter because the technique of tableting using commercially available tablet press is well recognized as part of the ordinary capabilities of the skilled artisan so that it would have been obvious to prepare caplets having desired dimensions of length and diameter. In the absence of factual evidence, caplet having the recited dimensions of length and diameter is not inventive over the caplet of the prior art that is silent on the dimensions of the caplet keeping in mind that caplets inherently have length and diameter.

7. Claims 3-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 5,869,097).

Wong teaches osmotic caplets comprising magnesium stearate (meets the lubricant of the claims), microcrystalline cellulose a9meeting the compressible materials of the claims) and drugs selected from omeprazole, nizatidine, bifentidine, erbrotidine, nifentidine, roxatidine, lansoprazole, amrinone, bepridil, diltiazem, felodipine, fendiline, flunarizine, nicardipine, isradipine, nifedipine, nimodipine, nisoldipine, nitredipine, perhexiline, amlodipine, nilvadipine, prenylamine, verapamil, cinnarizine, gallopamil, belfosdil, and fostedil (claims 3 and 5; Examples 1, 5 and 10-12). In Example 10, a caplet of 22 mm length and 8.5 mm in diameter at the center is made. Regarding the amount of the lubricant of claim 27, there is no demonstration that the "up to 5%" of lubricating material provides unexpected results and further, it is within the ordinary knowledge of the artisan to use adequate amounts of lubricant as tableting aid required to provide tablet/caplet having the desired hardness, tablet injection from the tablet press/punch press. It is noted that Wong contemplates formulating the caplet using many more drugs as listed in column 8, line 15 to column 9, line 49; so that it would be obvious to successfully formulate many more drugs including those recited in claims 3-8, 14-15 and 19-21 according to the teachings of Wong.

The difference between the claims and Wong is that Wong, at least in Example 10, makes a larger caplet as it regards the dimensions. However, it would have been obvious to prepare the caplet having desired dimensions of length and diameter because the technique of tableting using commercially available tablet press is well recognized as part of the ordinary capabilities of the skilled artisan so that it would have been obvious to prepare caplets having desired dimensions

of length and diameter. In the absence of factual evidence, caplet having the recited dimensions of length and diameter is not inventive over the caplet of Wong.

8. Claims 3-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cupps et al. (US 5,541,210).

Cupps describes caplet formulation that contains naproxen or loratidine, magnesium stearate, talc and microcrystalline cellulose (column 27, lines 5-10 and 33-48). The stearate and the microcrystalline cellulose meets the requirements of the instant dosage form for lubricant and the compressible material of instant claim 25. Cupps contemplates formulating dosage form containing other drugs such as dimenhydrinate and meclizine (column 19, lines 24,51, 52) with the dimenhydrinate meeting claims 13-15. The artisan, using the reference of Cupps would also formulate the caplet dosage form using any drug including those recited in claims 3-12 and 16-24. Regarding the amount of the lubricant of claim 27, there is no demonstration that the "up to 5%" of lubricating material provides unexpected results and further, it is within the ordinary knowledge of the artisan to use adequate amounts of lubricant as tableting aid required to provide tablet/caplet having the desired hardness, tablet injection from the tablet press/punch press.

The difference between the claims and Cupps is that Cupps is silent on the dimensions of the caplet. However, it would have been obvious to prepare the caplet having desired dimensions of length and diameter because the technique of tableting using commercially available tablet press is well recognized as part of the ordinary capabilities of the skilled artisan so that it would have been obvious to prepare caplets having desired dimensions of length and diameter. In the absence of factual evidence, caplet having the recited dimensions of length and

diameter is not inventive over the caplet of the prior art that is silent on the dimensions of the caplet keeping in mind that caplets inherently have length and diameter.

Response to Applicant's Remarks:

No arguments are filed with the filing of the RCE. However, applicant's comments that new claim 25 reads on the elected species is noted. Although, the classes of drugs are different in the separate claims, all the claims are examined because any of the drugs recited can be formulated as a caplet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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